K030559
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JUN 3 0 2003

RÜSCH
INTERNATIONAL
Group Regulatory Affairs
A Subsidiary of Teleflex incorporated (USA)

Tall Pines Park
Jaffrey, NH 03452
(603) 532-7706
FAX (603) 532-8211 or 6108

510(k) Summary

1. Submitter Name, Address, and Date of Submission.

Karenann J. Brozowski
Group Regulatory Affairs Director
Rüsch International
Tall Pines Park
Jaffrey, New Hampshire 03452

Telephone: (603) 532-7706
Facsimile: (603) 532-6207

Contact: Same as above

2. Name of the Device, Common, Proprietary (if Known), and Classification.

Classification:

Class II, Product Code 79ESW, 21 CFR 878.3610

Common Name:

Esophageal Stent

Proprietary Name:

Rüsch Polyflex Stent for the Esophagus
with Introducer/Delivery System

3. Identification of the legally marketed device to which the submitter claims equivalence.

The Rüsch Polyflex Stent for the Esophagus with Introducer System is substantially equivalent to the Hood Esophageal Prosthesis, Boston Scientific Ultraflex™, Boston Scientific Wall Stent, Cook, Inc. Esophageal Z-Stent, and the Wilson-Cook Esophageal Prosthesis Set.

4. Description of the Device.

The Rüsch Polyflex Stent for the Esophagus with Introducer System consists of the Polyflex Stent, Introducer Sleeve, Stent Loader, Insertion Tube with Dilator, Soft Positioner, Stopper and Stent Clamp.

5. Intended Use of the Device.

The Rüsch Polyflex Stent for the Esophagus with Introducer System intended for use with Esophageal Stenoses, indications are: Stenting: Esophageal stenoses (strictures), such as stenting refractory benign and/or malignant strictures. Esophageal-respiratory-fistula. Maintaining esophagus lumen patency in esophageal strictures caused by intrinsic or extrinsic tumors.

6. Summary of Technological Characteristics.

The following technological characteristics are the same as or equivalent to predicate devices:

The stent is constructed with an integral polyester braid, which is surrounded by medical grade silicone. This is the same construction as Rüsch Polyflex Stent Kit, which was cleared under K 982614.

The product is delivered through the mouth via a delivery system as is the Wilson Cook Esophageal Prosthesis, the Boston Scientific Ultraflex or Hood Prosthesis.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 3 0 2003

Ms. Karenann J. Brozowski
Group Regulatory Affairs Director
Rüsch International
Tall Pines Park
JAFFREY NH 03452

Re: K030559
Trade/Device Name: Rüsch Polyflex Stent for the Esophagus with Introducer/Delivery System
Regulation Number: 21 CFR §878.3610
Regulation Name: Esophageal prosthesis
Regulatory Class: II
Product Code: 79 ESW
Dated: June 6, 2003
Received: June 10, 2003

Dear Ms. Brozowski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K030559

Device Name: Rüsch Polyflex Stent for the Esophagus with Introducer System

Indications for Use:

Stenting:

Esophageal stenoses (strictures), such as stenting refractory benign strictures and/or malignant strictures

Esophageal-respiratory-fistula

Maintaining esophagus lumen patency in esophageal strictures caused by intrinsic or extrinsic tumors

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ___
(Per 21 CFR 801.109)

David A. Segman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K030559